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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,366	03/15/2004	Edward F. Leonard	19240.145-US2	3154
56949	7590	03/23/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP COLUMBIA UNIVERSITY 399 PARK AVENUE NEW YORK, NY 10020			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/801,366

Applicant(s)

LEONARD ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 21-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-20 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/10/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Applicant's election of Group I, Species I (claims 1-20) in the reply filed on 3/14/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 21-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. the Election has been treated as an election without traverse as noted above.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 10-11 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2004/0009096 (hereinafter referred to as Wellman).

Wellman teaches a membraneless filtration device comprising three inlets (40, 41) and three outlets (43, 44) and a microfluidic extraction channel connected to three inlets and three outlets (see figure 10; paragraph [0060, 0067, 0068, 0071]). Recitation of “wherein laminar flows of a first extractor fluid, the sample fluid, and a second extractor fluid are established inside the extraction channel and wherein sheathing of the sample fluid by the first and second extractor fluids substantially limits contact between the sample fluid and the surfaces of the extraction channel” in claim 1 is an intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the

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claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Furthermore, claim 1 does not recite any particular structural connection of sources of first extractor fluid, sample fluid and second extractor fluid to particular inlets or outlets. Regarding claims 2-3, percentage of sample fluid being sheathed by the first and second extractor fluids are also intended use arose from laminar flow in the extraction channel. Regarding claim 4, Wellman teaches that some of water in blood exits the device with extractor fluid through an exit channel (44) (see paragraph 0068). Regarding claim 5, at low pressure differences, there is inherently no advective transport of molecules within the extraction channel but pure diffusion in laminar flow condition in the apparatus of Wellman. Regarding claims 6-7, 10 and 14-15, two inlets (40) are connected with dialysate and sample fluid e.g. blood is connected to other inlet channel (41) and the sample flow e.g. blood flow is between two dialysate flows (see figure 10). Regarding claim 11, Wellman teaches that toxins are removed from blood (see paragraph 0071).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7, 10-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,948,684 (hereinafter referred to as Weigl et al '684) in view of US Pat. Publication 2003/0034306 (Schulte et al). Weigl et al '684 teach a microfluidic device comprising three inlet channels (55A, 55B and 50) and a common outlet channel connected to a microfluidic channel (100) wherein laminar flows of reference streams (75A, 75B) of same composition and sample stream (80) are established in the microfluidic channel (100) and the sheathing of sample stream by the first two reference streams substantially limits contact between the sample stream and the surfaces of the microfluidic channel (100) (see figure 3; col. 24, line 62 - col. 25, line 45). Claims 1-4, 6-7 and 14 essentially differ from the apparatus of Weigl et al '684 in reciting three exit channels. Schulte et al teach a microfluidic device including multiple inlets and outlets connected to a microfluidic channel for establishing laminar flow and suggests that more or less inlets and/or outlets can be used depending on the microfluidic application or process for collecting sample of interest or waste or both (see figures 3-4; paragraphs 0023-0027). It would have been obvious to a person of ordinary skill in the art to modify the apparatus and method of Weigl et al '684 to provide separate outlets to collect separate fractions of extraction fluid and sample fluid. Regarding claim 5, Weigl et al '684 teach that larger particles show no significant diffusion within the time the streams are in contact with each other in flow channel (100) (see col. 23, lines 23-27). Regarding claims 10-11, Weigl et al '684 teach that sample stream is blood and small ions such as protons and sodium ions diffuse rapidly across the channels (see col. 10, lines 48-67). Regarding claims 12-13, Weigl et al '684 teach the use of syringes in inlets and

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pumps in the outlet to adjust flow rate to accomplish equilibration of diffusion (see col. 17, lines 4-13; col. 24, lines 30-32; col. 28, lines 7-31). Regarding claim 16, Weigl et al '684 teach that the channel has a depth of at least about 200 micrometers (see col. 16, lines 12-16).

7. Claims 15 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684 in view of Schulte et al as applied to claim 1 and 14 above, and further in view of US 2002/0052571 (hereinafter referred to as Fazio). Claim 15 essentially differs from the apparatus of Weigl et al '684 in view of Schulte et al in reciting that the source of sample fluid is a human being connected to a second inlet channel. Fazio teaches an extracorporeal artificial kidney comprising microfluidic channels wherein blood from a human being is provided to an inlet manifold of the microfluidic channels (see abstract; figures 2-3; paragraphs 0013-0016). It would have been obvious to a person of ordinary skill in the art to connect an inlet channel of Weigl et al '684 to human being to arrive at an artificial kidney to remove waste out of blood stream by dialysis. Regarding claims 18-19, Fazio teaches that waste dialysate collected from the microfluidic channels are transferred to the patient's bladder for elimination through the urinary tract wherein human bladder are made of membranes (see paragraph 19). It would have been obvious to a person of ordinary skill in the art to include a membrane device connected to membraneless exchange device to receive, temporarily store and remove waste dialysate.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684 in view of Schulte et al and Fazio as applied to claim 18 above, and further in view of US Pat. No. 4,661,246 (hereinafter referred to as Ash). Claim 20 essentially differs from the apparatus of Weigl et al '684 in view of Schulte et al and Fazio in reciting a sorption device. Ash teaches an extracorporeal artificial kidney comprising a sorption column (48) for removing urea from waste

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dialysate to regenerate dialysate (see figure 2; col. 4, lines 46-63; claim 5). It would have been obvious to a person of ordinary skill in the art to provide a sorbent column in the apparatus of Weigl et al '684 in view of Schulte et al and Fazio to regenerate waste dialysate to be reused.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684 in view of Schulte et al as applied to claim 1 above, and further in view of US Pat. No. 5,932,100 (hereinafter referred to as Yager et al '100). Claim 17 essentially differs from the apparatus of Weigl et al '684 in view of Schulte et al in reciting that the extraction channel has a width-to-height ratio of at least 10. Yager et al '100 teach that the microfluidic extraction channel having an aspect ratio of width to depth ratio of less than 50 allows significant minimization of the device size at moderate extraction channel flow rate as well as lower flow rates (see col. 8, lines 34-55). It would have been obvious to a person of ordinary skill in the art to modify the microfluidic channel of Weigl et al '684 in view of Schulte et al to have a width-to-height ratio of at least 10 to provide distinctive advantages suggested by Yager et al '100 in significant minimization of the device size at moderate extraction channel flow rate as well as usage of lower flow rates.

10. Claims 8-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Kim
Primary Examiner
Art Unit 1723

JK
March 21, 2006